IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| **SMITHKLINE BEECHAM CORPORATION,** | **:** | |
| **SMITHKLINE BEECHAM, P.L.C., and** | **:** | **CIVIL ACTION** |
| **BEECHAM GROUP, P.L.C.** | **:** | **NO. 99-CV-4304** |
| | **:** | **NO. 00-CV-4888** |
| **v.** | **:** | **NO. 01-CV-0159** |
| | **:** | **NO. 01-CV-2169** |
| **APOTEX CORPORATION, APOTEX, INC.** | **:** | |
| **and TORPHARM, INC.** | **:** | |
| | **:** | |
| **v.** | **:** | |
| | **:** | |
| **SMITHKLINE BEECHAM CORPORATION,** | **:** | |
| **SMITHKLINE BEECHAM, P.L.C.,** | **:** | **CIVIL ACTION** |
| **BEECHAM GROUP, P.L.C.,** | **:** | **NO. 99-CV-4304** |
| **GLAXOSMITHKLINE, P.L.C.,** | **:** | |
| SMITHKLINE BEECHAM CORPORATION, | : | |
| SMITHKLINE BEECHAM, P.L.C. and | : | CIVIL ACTION |
| BEECHAM GROUP, P.L.C. | : | NO. 99-CV-2926 |
| | : | NO. 00-CV-5953 |
| v. | : | NO. 02-CV-1484 |
| | : | |
| GENEVA PHARMACEUTICALS, INC. | : | |
| and SUMIKA FINE CHEMICALS CO., LTD. | : | |
| SMITHKLINE BEECHAM CORPORATION, | : | |
| SMITHKLINE BEECHAM, P.L.C. and | : | CIVIL ACTION |
| BEECHAM GROUP, P.L.C. | : | NO. 00-CV-1393 |
| | : | NO. 00-CV-6464 |
| v. | : | NO. 01-CV-2602 |
| | : | |
| ZENITH GOLDLINE PHARMACEUTICALS, | : | |
| INC. and SUMIKA FINE CHEMICALS CO., LTD. | : | |
| SMITHKLINE BEECHAM CORPORATION, | : | |
| SMITHKLINE BEECHAM, P.L.C. and | : | CIVIL ACTION |
| BEECHAM GROUP, P.L.C. | : | NO. 01-CV-1027 |
| | : | NO. 01-CV-3364 |
| v. | : | NO. 02-CV-8493 |
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| ALPHAPHARM PTY, LTD. and | : | |
| SUMIKA FINE CHEMICALS CO., LTD. | : | |

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| SMITHKLINE BEECHAM CORPORATION, | : | |
| and BEECHAM GROUP, P.L.C. | : | CIVIL ACTION |
| | : | NO. 01-CV-2981 |
| v. | : | NO. 03-CV-6117 |
| | : | |
| BASF CORPORATION, | : | |
| BASF PHARMACHEMIKALIEN GMBH & CO. | : | |
| KG and KNOLL AG. | : | |

**SURRICK, J.** **JANUARY 31, 2006**

**MEMORANDUM & ORDER**

Presently before the Court is Defendants Apotex Corp., Apotex, Inc., And TorPharm, Inc.'s (collectively "TorPharm" or "Defendant") Motion To Compel Production Of Documents (Doc. No. 185, 99-CV-4304; Doc. No. 142, 00-CV-4888; Doc. No. 137, 01-CV-159; Doc. No. 128, 01-CV-2169). For the following reasons, Defendant's Motion will be granted.

## I. BACKGROUND[1]

These consolidated cases involve claims by Plaintiff SmithKline Beecham Corp. ("Plaintiff" or "GSK") of patent infringement. The patents at issue cover certain forms of paroxetine hydrochloride, processes for making paroxetine hydrochloride, and uses of paroxetine hydrochloride.

GSK manufactures paroxetine hydrochloride, and then tablets and sells that product in the United States under the trademark Paxil® ("Paxil"). Paxil is an antidepressant drug used to treat a variety of disorders and is one of the most widely prescribed drugs in the United States.

[1] Additional background regarding this litigation and the applicable statutory framework may be found in our Memoranda and Orders dated September 28, 2001, September 30, 2002, October 31, 2002, December 20, 2002, September 29, 2004, and March 31, 2005. (Doc. Nos. 50, 71, 77, 85, 165, 182.) Unless otherwise specified, all docket numbers cited in this Memorandum refer to the filings in Civil Action No. 99-4304.

TorPharm is a generic drug manufacturer that seeks to sell a generic version of Paxil. GSK claims that TorPharm's generic products and/or methods of manufacturing the same infringe one or more of GSK's patents. In March 1998, Defendant became the first generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration seeking its approval to market a generic version of Paxil.[2]

Defendant submitted its ANDA for a generic version of Paxil on March 31, 1998. The active ingredient listed in Defendant's ANDA is a form of paroxetine hydrochloride and a bioequivalent of Paxil's active ingredient. In response to the ANDA, GSK filed five lawsuits alleging that Defendant's production of the generic drug would infringe several patents held by GSK.[3] On September 28, 2001, the four lawsuits filed in this District were consolidated for

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[2] Pursuant to the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act ("Hatch-Waxman"), Pub. L. No. 98-417, 90 Stat. 1585 (1984) (codified in scattered sections of 21, 35, and 42 U.S.C.), a generic drug manufacturer may seek expedited approval to market a generic version of a previously approved drug by submitting an ANDA to the FDA. 21 U.S.C. § 355(j). TorPharm filed its ANDA under "Paragraph IV," in which the applicant certifies that the "patent is invalid or will not be infringed by the drug for which the application seeks approval." 21 U.S.C. § 355(j)(A)(vii). A more detailed summary of Hatch-Waxman's procedures for submission and approval of an ANDA may be found in our Memoranda and Orders of September 28, 2001, December 20, 2002, July 16, 2004, and September 29, 2004. (Doc. Nos. 50, 85, 165.)

[3] The first action, filed in the Northern District of Illinois (No. 98-CV-3952) on June 26, 1998, alleges infringement of U.S. Patent No. 4,721,723 (the "'723 Patent").

In this District, GSK filed Civil Action No. 99-CV-4304 on August 26, 1999, alleging infringement of U.S. Patent No. 5,900,423 (the "'423 Patent"). On September 27, 2000, GSK filed Civil Action No. 00-CV-4888, alleging infringement of U.S. Patent No. 6,080,759 (the "'759 Patent") and seeking declaratory judgment that Defendant's future commercial manufacture and sale of its paroxetine hydrochloride product would infringe the process claims of the '759 Patent. Civil Action No. 01-CV-159, filed on January 11, 2001, alleges infringement of U.S. Patent No. 6,133,944 (the "'944 Patent"). GSK filed Civil Action No. 01-CV-2169 on May 2, 2001, alleging infringement of U.S. Patent No. 6,172,233 (the "'233 Patent") and seeking a declaratory judgment that the process claims of the '233 Patent would be infringed by Defendant's future commercial manufacture and sale of its proposed paroxetine hydrochloride

purposes of pretrial discovery. *SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, Nos. 99-2925 et al., 2001 U.S. Dist. LEXIS 14434, at *23 (E.D. Pa. Sept. 28, 2001).

In the instant Motion, TorPharm seeks to compel production of three categories of documents: (1) those related to the identities, responsibilities and actions of GSK groups involved in Plaintiff's Post-Patent Strategy (Req. Nos. 490-505); (2) those related to GSK's communications with the United States Pharmacopeia ("USP"), British Pharmacopoeia ("BP"), and Eurpoean Pharmacopoeia ("EP") (Req. Nos. 506-08); and (3) those related to the PAR/Pentech Agreement (Req. Nos. 536-39, 554-55, 557-63, 566-67). (Doc. No. 185 at 4-14.) Defendant argues this evidence is relevant to the counterclaims and affirmative defenses raised in its Second Amended Answer (Doc. No. 103). (Doc. No. 185 at 1.) In its counterclaims, Defendant contends GSK's "Post-Patent Strategy" constituted an "anticompetitive and tortious scheme to maintain [GSK's] monopoly power in the paroxetine market by hindering TorPharm's ability to compete." (*Id.*) These claims are based, in part, on GSK's licensing agreement with PAR Pharmaceuticals, Inc. and Pentech Pharmaceuticals, Inc. ("the PAR/Pentech Agreement") and on its alleged "deliberate[] attempt[] to influence the USP, BP, and EP to adopt standards that generic[ drug manufacturers] could not meet." (Doc. No. 103 at Ex. A ¶¶ 5, 309-46; Doc. No. 185 at 10.)

At present, both parties agree that Defendant's Motion is moot with respect to Document Requests 490-505. GSK has agreed to produce these documents. (Pl.'s Memo. in Opp'n, Doc. No. 190 at 4-5; Def.'s Reply Memo. in Supp., Doc. No. 194 at 7.) GSK has also satisfied Request 506 by producing its submissions to the USP. (Doc. No. 190 at 3; Doc. No. 194 at 1-2.)

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product.

Therefore, we will address only TorPharm's requests with respect to the foreign pharmacopoeial organizations and the PAR/Pentech Agreement.

## II. LEGAL STANDARD

Federal Rule of Civil Procedure 26(b)(1) permits litigants to "obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party." The information sought in discovery need not be admissible, as long as it "appears reasonably calculated to lead to discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). Relevance is generally construed broadly. *See Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) (citing *Hickman v. Taylor*, 329 U.S. 495, 501 (1947)). As such, the liberal discovery permitted by the Federal Rules of Civil Procedure ensures that no relevant facts remain hidden. *Northern v. City of Phila.*, Civ. A. No. 98-6517, 2000 U.S. Dist. LEXIS 4278, *1 (E.D. Pa. 2000). Where a party receives evasive or incomplete answers to a discovery request, they are permitted to bring a motion to compel disclosure. *See* Fed R. Civ. P. 37(a)(3).

However, the court is permitted to limit "the frequency or extent of use of the discovery methods" where it find that

> (i) the discovery sought is unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive; (ii) the party seeking discovery has had ample opportunity by discovery in the action to obtain the information sought; or (iii) the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

Fed. R. Civ. Pro. 26(b)(2). The party resisting production bears the burden of persuasion. *See Fid. & Deposit Co. of Md. v. McCulloch*, 168 F.R.D. 516, 520 (E.D. Pa. 1996). The resisting

party "must show specifically" how the information requested "is not relevant or how each question is overly broad, burdensome or oppressive." *Josephs v. Harris Corp.*, 677 F.2d 985, 992 (3d Cir. 1982). "Mere recitation of the familiar litany that an interrogatory or document production request is 'overly broad, burdensome or oppressive' will not suffice." *Momah v. Albert Einstein Med. Ctr.*, 164 F.R.D. 412, 417 (E.D. Pa. 1996) (quoting *id.* at 992). "[W]here there is doubt over relevance, the rule indicates that the court should be permissive" in granting the discovery request. *Stabilus v. Haynsworth, Baldwin, Johson & Greaves, P.A.*, 144 F.R.D. 258, 265 (E.D. Pa. 1992).

## III. DISCUSSION

### A. Documents Related to GSK's Communications with the BP & EP Concerning Paroxetine

The USP, BP, and EP are private, independent, pharmacopoeial organizations that compile specifications (in the U.S., Great Britain, and Europe, respectively) for individual drugs and drug products. (Doc. No. 185 at 10.) The pharmacopoeias publish these specifications in the form of monographs, which serve to establish standards for use by the scientific community during drug production. (*Id.*)

TorPharm argues that GSK's communications with the BP and EP are "likely to lead to admissible evidence concerning TorPharm's monopolization and attempted monopolization counterclaims[,]" as well as its affirmative defenses. (Doc. No. 194 at 2-3.) As part of its Post-Patent Strategy, GSK sought to influence the standards promulgated by the three pharmacopoeial organizations in order to inhibit generic manufacturers from entering the paroxetine market. (*Id.* at 2.) GSK intended to accomplish this by "creating specs which represent[ed its] position on the

learning curve thereby making it more difficult, costly and time consuming for a generic to catch up." (*Id.*) As a further justification for its production, TorPharm also contends the analytical test data submitted to the BP and EP is relevant to its affirmative defenses. (*Id.* at 3.)

In an attempt to avoid production, GSK argues that because the BP and EP are foreign, its submissions to these organizations cannot be relevant to an alleged scheme to monopolize the domestic market for paroxetine. GSK also claims that the analytical test data submitted to the BP and EP is identical to data submitted to the USP and already produced. We are not persuaded by either argument.

It is clear that communications between a corporation and a standards-setting organization can form the basis of an antitrust claim. *Allied Tube & Conduit Corp v. Indian Head, Inc.*, 486 U.S. 492, 499-500 (1988); *Rambus Inc. v. Infineon Techs. AG*, 330 F. Supp. 2d 679, 696-97 (E.D. Va. 2004). Antitrust cases, particularly those involving allegations of monopolization, call for "broad discovery . . . to uncover evidence of invidious design, pattern, or intent." *Am. Health Sys., Inc. v. Liberty Health Sys*., Civ. A. No. 90-3112, 1991 U.S. Dist. LEXIS 2612, at *7 (E.D. Pa. Mar. 5, 1991) (citing *Kellam Energy, Inc. v. Duncan*, 616 F. Supp. 215, 217 (D. Del. 1985)). This concept applies equally to geographic scope and justifies discovery of evidence concerning GSK's foreign activities: "The fact that the United States is the relevant market in [a] case does not necessarily limit discovery to the United States." *United States v. Dentsply Inter'l, Inc.*, Civ. A. No. 99-5, 2000 U.S. Dist. LEXIS 6925, at *17 (D. Del. May 10, 2000) (citing *Kellam Energy, Inc.*, 616 F. Supp. at 219), *rev'd on other grounds*, 399 F.3d 181 (3d Cir. 2005), *cert. denied*, 2006 U.S. LEXIS 33 (Jan. 9, 2006).

GSK's claim that these requests are duplicative is also open to question. GSK has already provided certain of its correspondence with the BP and EP concerning paroxetine hydrochloride's melting point. (*Id.*) GSK did not object to this earlier discovery. GSK argues TorPharm has broadened its discovery request, without initial discussion, in the instant Motion. We find no merit in this contention. (*See* Doc. No. 185 at Ex. C (seeking "any communications between [GSK] and BP or EP regarding testing").) In any event, TorPharm should be entitled to evaluate whether the data submitted to the BP and EP are identical to the USP data. We conclude that the submissions to the BP and EP have sufficient independent relevance to warrant their production. This discovery "appears reasonably calculated to lead to discovery of admissible evidence" concerning TorPharm's antitrust counterclaims and affirmative defenses. The mere fact that the BP and EP are foreign entities should not preclude this discovery. Therefore, GSK will be compelled to comply with Document Requests 507 and 508.

**B. Documents Related to the PAR/Pentech Agreement**

PAR and Pentech ("PAR/Pentech") were joint venture partners and defendants in the patent infringement action brought by GSK in the Northern District of Illinois (No. 98-CV-3952). *See SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 694 (E.D. Pa. 2004). On April 18, 2003, GSK and PAR/Pentech entered into a series of agreements, the purpose of which was to settle that lawsuit and grant PAR/Pentech a license to market a generic form of Paxil under certain circumstances. *Id*. The PAR/Pentech Agreement in question ("the Agreement") allows PAR/Pentech to compete with TorPharm in the generic Paxil market during

the 180 day-period in which Defendant expected to enjoy market exclusivity.[4] *Id.* We have already determined that the PAR/Pentech Agreement did not itself produce an antitrust injury. *Id.* at 702 (dismissing certain counterclaims against GSK and all counterclaims against Par and Pentech). However, our ruling did not preclude the possibility that GSK entered into the Agreement "as part of a larger scheme to maintain its monopoly in the market for paroxetine hydrochloride." *Id.*

GSK now argues that discovery in this area must be tailored to reflect our earlier opinion. (Doc. No. 190 at 9-10.) Plaintiff claims that all relevant documents related to the Agreement "would be covered by other requests to which GSK has agreed to respond." However, Plaintiff does not specifically identify which production requests would be duplicative. (*Id.* at 10; Doc No. 185 at Ex. F.) Nor does Plaintiff attempt to guide us as to what boundaries might be placed on TorPharm's discovery so that it is less objectionable to Plaintiff. GSK's allegation of overbreadth lacks specificity and fails to convince us that TorPharm is not entitled to liberal discovery regarding the PAR/Pentech agreement. (*Id.* at 10.) The Agreement between GSK and PAR/Pentech may form an element in TorPharm's antitrust counterclaims. Antitrust is an area in which particularly broad discovery is encouraged. *Kellam Energy, Inc.*, 616 F. Supp. at 217. As such, discovery concerning the PAR/Pentech agreement should not be limited. Accordingly, GSK must comply with TorPharm's Document Requests 536-39, 554-55, 557-63, and 566-67.

An appropriate Order follows.

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[4] The Hatch-Waxman Amendments grant the first entity to file an ANDA with a Paragraph IV certification a 180-day period to market the generic drug before any subsequent ANDA that contains a Paragraph IV certification is made effective. 21 U.S.C. § 355(j)(5)(B)(iv).

IN THE UNITED STATES DISTRICT COURT
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| **SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM, P.L.C., and BEECHAM GROUP, P.L.C.** | : | **CIVIL ACTION NO. 99-CV-4304 NO. 00-CV-4888 NO. 01-CV-0159 NO. 01-CV-2169** |
| **v.** | : | |
| **APOTEX CORPORATION, APOTEX, INC. and TorPharm, INC.** | : | |
| **v.** | : | |
| **SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM, P.L.C., BEECHAM GROUP, P.L.C., GLAXOSMITHKLINE, P.L.C.,** | : | **CIVIL ACTION NO. 99-CV-4304** |
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| v. | : | |
| ALPHAPHARM PTY, LTD. and SUMIKA FINE CHEMICALS CO., LTD. | : | |

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| SMITHKLINE BEECHAM CORPORATION, and BEECHAM GROUP, P.L.C. | : | CIVIL ACTION |
| | : | NO. 01-CV-2981 |
| v. | : | NO. 03-CV-6117 |
| | : | |
| BASF CORPORATION, BASF PHARMACHEMIKALIEN GMBH & CO. KG and KNOLL AG. | : | |

**ORDER**

AND NOW, this 31st day of January, 2006, upon consideration of Defendants Apotex Corp., Apotex, Inc., And TorPharm, Inc.'s Motion To Compel Production Of Documents (Doc. No. 185, 99-CV-4304; Doc. No. 129, 00-CV-4888; Doc. No. 137, 01-CV-159; Doc. No. 128, 01-CV-2169), it is ORDERED that the Motion is GRANTED, consistent with the attached Memorandum.

IT IS SO ORDERED.

BY THE COURT:

S:/R. Barclay Surrick, Judge